

Attachment 4

Drug Counterfeiting Articles

ILLEGAL VIAGRA LEADS 24% JUMP IN COUNTERFEIT MEDICINE SEIZURES

By Allan Dodds Frank

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June 10 (Bloomberg) -- Counterfeit medicines are on the rise worldwide, as criminals capitalize on the growing use of the Internet by consumers searching for inexpensive drugs.

Seizures of bogus prescription medicines jumped 24 percent to 1,513 incidents in 2007, and illicit versions of 403 different prescription drugs were confiscated in 99 countries, according to the Pharmaceutical Security Institute, a Vienna, Virginia-group funded by 26 drugmakers. The \$3 billion in counterfeit drugs seized include generic copies that violate patent laws and products that lack active chemical ingredients or contain improper dosages.

In the decade since Internet sites began selling illegal copies of Pfizer Inc.'s erectile dysfunction drug Viagra, counterfeiters have diversified, marketing pills to treat heart disease, arthritis, asthma, AIDS and cancer, according to the institute, which has been monitoring product seizures since the group was formed in 2002.

Copies of 19 of the world's 25 best-selling drugs were among those seized by industry security, customs agents and police last year at ports of entry, in free-trade zones or at illicit manufacturing and distribution sites, according to data compiled by Bloomberg.

"It's a big issue, it's a global issue, it's an insidious issue," said John Lechleiter, Eli Lilly & Co.'s president and chief executive officer, in an interview at his Indianapolis headquarters.

Lost Sales

New York-based Pfizer, the world's largest drug-maker, estimates it may be losing sales of \$2 billion a year in Viagra alone, given how much of the drug's active ingredient is produced in India and shipped abroad, says Rubie Mages, a company director of global anti-counterfeiting. Sales of the impotence drug in 2007 totaled \$1.8 billion.

"Over the past six years we've seen double-digit increases around the world" of counterfeit drug seizures, said Thomas Kubic, a former U.S. Federal Bureau of Investigation agent who is executive director of the pharmaceutical institute, in an interview at his office in Virginia.

"Often times, the drugs that are being sold emanate from China, from Russia and from India," says Steven Rucker, an executive managing director of Kroll Inc., a New York security firm used by pharmaceutical companies to track down counterfeiters.

Rucker says in the last two years, Kroll has worked for 10 drug and medical device companies, though he says confidentiality agreements prevent him from identifying them.

China, India

Fake versions of Pfizer's Viagra and its impotence pill competitors -- Levitra from Leverkusen, German-based Bayer AG and Schering-Plough Corp. of Kenilworth, New Jersey, and Cialis from Eli Lilly -- have been traced to manufacturers in China and India.

"Our awareness of the extent of counterfeiting came about mainly as a result of Cialis," says Lechleiter of Indianapolis-based Lilly. "But the problem is not restricted to Cialis. We've seen counterfeit versions of other Lilly products emerge in markets around the world"

Counterfeits of Lilly's top seven products, led by the anti-psychotic drug Zyprexa, and more than two million tablets of Cialis, were seized in 800 raids around the world last year, Lilly security officials say. The top seven drugs made by Lilly generated 68 percent of the company's \$17.6 billion in sales of human medicine in 2007.

Seizures in 45 countries last year found counterfeits of Pfizer's nine best-selling drugs, including fakes of Lipitor, the cholesterol pill that accounts for one-quarter of Pfizer's \$48 billion in sales. Illegal copies of Pfizer's eight other top drugs, which account for another 30% of sales, also were seized.

Most Counterfeited

Pfizer's Mages says Viagra remains the world's most-counterfeited drug and accounted by volume for almost three-quarters of the illicit copies of Pfizer brands seized last year in 45 countries. The drugs are marketed on Internet sites whose operations are also global, she says.

While a portion of drugs identified as counterfeit lack proper ingredients or contain incorrect and misidentified dosages, authorities have also seized chemically identical duplicates created by manufacturers in China and India and shipped to the U.S. or Europe in violation of patent laws.

U.S. Food and Drug Administration officials say they are unable to stop the flow of illegal drugs sold on the Internet.

“There are counterfeiters circulating all over the world,” says Ilisa Bernstein, director of pharmacy affairs at the Rockville, Maryland-based FDA. “It’s hard to tell how many there are because the counterfeiters are just so good at what they do.”

The agency can’t police all the international drug shipments referred to the FDA by U.S. Customs and Border Protection Inspectors at post offices, she says.

‘Millions and Millions’

“There are millions and millions and millions of these packages coming in at international mail facilities each year,” Bernstein says. “It’s very difficult to find and catch all of these drugs that are coming in to protect patients from all these very risky drugs.”

The FDA’s claim that it can’t destroy counterfeits is disputed by Representative Steven Buyer, an Indiana Republican. “The FDA does not destroy it, the FDA becomes the enabler of the counterfeiters,” says Buyer, who predicts counterfeit drugs will be a \$100 billion global business in five years.

Representative Bart Stupak, a Michigan Democrat who chairs the House Energy & Commerce Subcommittee on Oversight & Investigations, says the FDA’s failure to act has contributed to the flow of counterfeit drugs into the U.S. Stupak says he has repeatedly asked the FDA if it needs new laws passed to strengthen enforcement and they “have remained silent.”

Health Damage

Few law enforcement agencies make stopping counterfeit drugs a priority, says James Christian, vice president for corporate security for Basel, Switzerland-based Novartis AG, which is investigating sales of counterfeit versions of its hypertension drug, Diovan.

“When you are talking about where manufacturing is taking place, where distribution is taking place, where the printing of the counterfeit inserts and packaging is taking place, these cases are 99 percent made by the industry,” says Christian.

It is unclear how much, if any, health damage is caused by the counterfeiting. The World Health Organization says 10 percent of the drugs worldwide may be counterfeit, with more than 50 percent of the medicines that are shipped to some countries not containing the proper ingredients.

The Geneva-based WHO estimates that tens of thousands of people may be dying from counterfeit drugs used to treat malaria, HIV/AIDS, diabetes and tropical diseases. The deaths are hard to identify since people die partly as a result of getting no effect from the treatments they are taking, according to Valerio Reggi, executive director of WHO’s International Medical Products Anti-Counterfeiting Taskforce.

Fake Pharmacies

Millions of Americans buying from the Internet are at risk, says Frederick Felman, executive marketing director for MarkMonitor, a San Francisco company that helps drugmakers protect their trademarks on the Internet. While there are fewer than 300 online pharmacies in Canada authorized by government agencies, more than 11,000 fake Canadian pharmacies are operating online from overseas jurisdictions, Felman says.

Mark Kolowich, one of the few Americans convicted of drug counterfeiting, says he sold more than \$20 million of illegal copies of erectile dysfunction drugs and other medicines through a series of Web sites before being arrested in San Diego and pleading guilty in 2004.

Now 48, Kolowich served almost three years in federal prison in California and remains on probation in San Diego, where he lives. Kolowich says he used the Internet to find finished pills and active pharmaceutical ingredients from China, India and elsewhere. He also sold knockoffs of Viagra, Merck & Co.'s baldness drug Propecia; Pfizer's Lipitor and its painkiller Celebrex; and Lilly's Cialis, to as many 65,000 customers, from late 1998 until his arrest in March 2004.

"If you are on the Internet, people can't really tell if you're a big operator or a reputable operator, who you are as long as you can make that website look pretty impressive," Kolowich says.

-- With reporting by Jaime Hellman, Elizabeth Lopatto and Wendy Soong in New York. Editor: Michael Waldholz, Jeffrey Tannenbaum, Antony Michels, Karin Annus

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Internet Drugs? Be Careful

By Steven Marks

Although Internet drug purchasing is known to be a dicey proposition, the extent of the risk has never been established. A new report by the European Alliance for Access to Safe Medicine (EAASM), the results of which were released last week at the 4th Global Forum on Pharmaceutical Anticounterfeiting, suggests the problem may be worse than regulatory agencies heretofore anticipated. In fact, more than half (62%) of all medicines bought on-line were fakes, and nearly 96% of the virtual pharmacies under study operated illegally, according to Jim Thomson, chair of the patients' rights group, which is based in Surrey, UK.

"The results of our investigation are shocking," he told the Forum. "It is astonishing to me that if I input 'buy Viagra' on my computer, I will get nearly 12 million hits. On the other hand, if I enter 'child porn,' I will get nothing."

The EAASM study, called "The Counterfeiting Superhighway,"* was designed to determine the proportion of internet pharmacies that act unlawfully and the percentage of counterfeit or substandard drugs that are sold. The researchers assessed more than 100 websties, ordering such cardiovascular, respiratory, psychotropic, neurologic, and men's health medications as Lipitor, Plavix, Spiriva, Zyprexa, Efexor, Risperdal, Aricept, and Viagra. Experts then performed visual and laboratory analysis of the compounds. In addition to the primary findings, the EAASM reported that more than 90% of websites supplied prescription-only drugs without a prescription, 94% of the websites did not have the required pharmacist identified on the site, and 86% of online pharmacy approval stamps were fraudulent. One phony Plavix order came packed in newspaper, with free Viagra samples dropped into the wrapper as a bonus, Thomson said.

"We call on all stakeholders, including search engines, credit card companies, shipping companies, patients and regulators to take appropriate action," he states. "Online pharmaceutical purchasing has already killed people; if stakeholders don't address the problem immediately, millions will die."

First Meeting in US

The Global Forum on Pharmaceutical AntiCounterfeiting is a yearly gathering of experts from the pharmaceutical industry, international and national drug and regulatory agencies, consumer groups, and the anticounterfeiting technology industry. This year's meeting, the first to be held in the US, addressed "Systems for Safety in a Global Arena." The speakers and attendees agreed that, despite current enforcement efforts, the drug counterfeiting business is booming around the globe. Both developed and developing nations are affected, and the supply chain is riddled with weak links through which the unscrupulous manufacturer and trader in phony pharmaceuticals prey on the unwary consumer. Of particular concern is the parallel trade, a complex process by which a third-party wholesaler or intermediary buys low-cost pharmaceuticals from one country, say, Spain, and then sells them in a second country, England, at a higher price. The problem, as Jonathan Harper, MD, an expert on parallel trade and the author of a detailed report on the ways in which the process threatens patient safety, is that parallel trading practices take place outside the manufacturer's or licensed distributor's formal channels. This lack of oversight creates the opportunity for mischief, for the entry of counterfeit drugs into regulated chains of supply and distribution.

"The rationale for parallel trading is that it is always good to price shop," Harper told the audience. "However, the process is largely invisible and under-regulated. The parallel trade weakens the supply chain and, most important, compromises drug safety."

Parallel trading is a particular problem in Europe because the system is legal, and the various EU members have different drug pricing systems. As Roger Bate notes in his new book *Making a Killing: The Deadly Implications of the Counterfeit Drug Trade*, parallel trading functions much like arbitrage, in which brokers leverage price differences for a profit.¹ Although arbitrage can improve market efficiency by leveling out price differences, the drug market is different from most. The high cost of pharmaceutical research and developments skews the price in wealthier markets to a point above the marginal costs of production. More ominously, by increasing the number of middlemen, arbitrage multiplies the opportunity for counterfeiters to slip phony medicines into the legitimate supply chain.

"It is possible that parallel trading provides savings to payers, although this is debatable," Harper said. "However, the value that is added goes largely to intermediary traders." Moreover, he reported that the parallel trade in pharmaceuticals creates unnecessary supply system stress. It also introduces additional regulatory costs and burdens, undermines the guarantee of continuous supply, reduces incentives to invest in R&D, provides only marginal health benefit, and most important, puts patient safety in jeopardy.

"It is high time to review and codify the case law on parallel pharmaceutical trading," Harper concluded. "We also need to strengthen global trade and regulatory agreements. Patients are already at risk, and this risk will worsen if we do not act quickly."

Drug Re-Importation a Flawed Idea

In the US, parallel pharmaceutical trade is called "drug re-importation" and has been a hobby horse of so-called consumer rights groups and ill-informed politicians on both sides of the aisle for some time. But, as Peter Pitts, the president of the Center for Medicine in the Public Interest, said, the chance that an American president will ever sign a national drug re-importation law is somewhere between slim and none.

Despite what the presidential candidates say on the campaign trail, Pitts offered 4 reasons why the dangerous reality of drug re-importation

trumps the obvious political appeal of low-cost medicines. First, multiple analyses show that drug re-importation won't reduce healthcare costs. Second, Americans believe re-importation will allow access to well-regulated Canadian drugs. In fact, most of the drugs received by participants in the several state re-importation programs now in operation originate from either the European parallel trade or unregulated drug operations in Asia. Once Americans learn this unsavory truth, the promise of drug importation rapidly loses its appeal, as evidenced by reason three: fewer than 0.5% of citizens in states such as Maine, Minnesota, Illinois, Wisconsin, Kansas, Missouri, and Vermont who could join a state-run re-importation plan chose to do so. Fourth, drug re-importation cannot be done safely, especially when there is evidence that such life-saving medicines as Zyprexa, Plavix, human growth hormone, and cancer drugs have been repeatedly faked. Truth be told, Pitts stated, "the US experience with drug re-importation has been dismal and a political embarrassment." Those politicians and pundits who believe that the concerns for drug safety are a red herring are failing to act responsibly. Drug re-importation is a ticking time bomb.

Other important observations heard at the Global Forum:

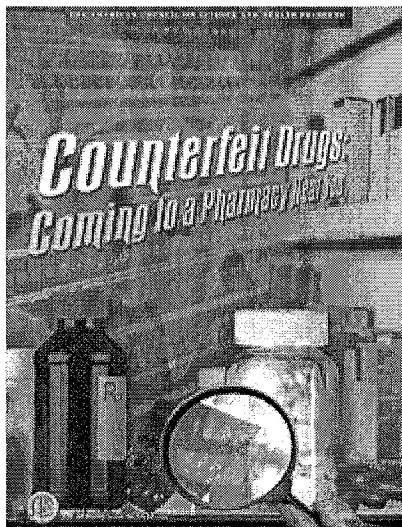
- Σ The low risk of detection and weak penalties for conviction make drug counterfeiting attractive to organized crime and narcotics dealers. Drug counterfeiting is seen as a patent-infringement problem, not a patient-safety matter. Laws pertaining to counterfeit drug trafficking must be revised so that the punishment fits the crime;
- Σ Oversight of the drug supply chain must be improved and those who are involved in the shipping, transfer, and distribution of pharmaceuticals must be held legally responsible for their actions. Sad to say, governments around the world hold tobacco wholesalers and shippers to a higher standard than those engaged in pharmaceutical traffic;
- Σ New technologies to improve authentication, tracking, and information sharing are now in development. These new systems must be made practicable for patients, healthcare professionals, manufacturers, custom officials, drug inspectors, and the police and should be flexible and adaptable for use in both developing and developed nations;
- Σ The pharmaceutical industry's belated acknowledgement of drug counterfeiting has fostered the development of well-coordinated international solutions, such as the World Health Organizations' International Medical Products Anti-Counterfeiting Taskforce (IMPACT). Unfortunately, progress has been slow, and the implementation of new technologies to ensure the authenticity of the supply chain are likely to be incremental;
- Σ Well-designed consumer education programs must be an essential part of the solution. Unless the public comes to appreciate its vital role in the detection and reporting of suspicious products, the implementation of new technologies to improve drug identification and authentication, such as 2-dimension holograms and radio frequency identification, will be only partially successful;
- Σ The various state pharmacy electronic programs to demonstrate drug authenticity from the manufacturing plant to the point of dispensing, a process known as "e-pedigree," have run into a number of glitches along the way to implementation. In the future, it is likely that a single national standard will be developed.

* The Counterfeiting Superhighway is available at www.eassm.eu.

1 Bates R. Making a Killing: The Deadly Implications of the Counterfeit Drug Trade. AEI Press, Washington, DC. 2008.

Steven Marks is a science writer whose report on Obesity and New Pharmaceutical Approaches is coming soon from the American Council on Science and Health (ACSH.org).

See also: ACSH's full 2006 report on *Counterfeit Drugs* (soon to be updated).



This information was found online at: http://www.acsh.org/factsfears/newsID.1163/news_detail.asp

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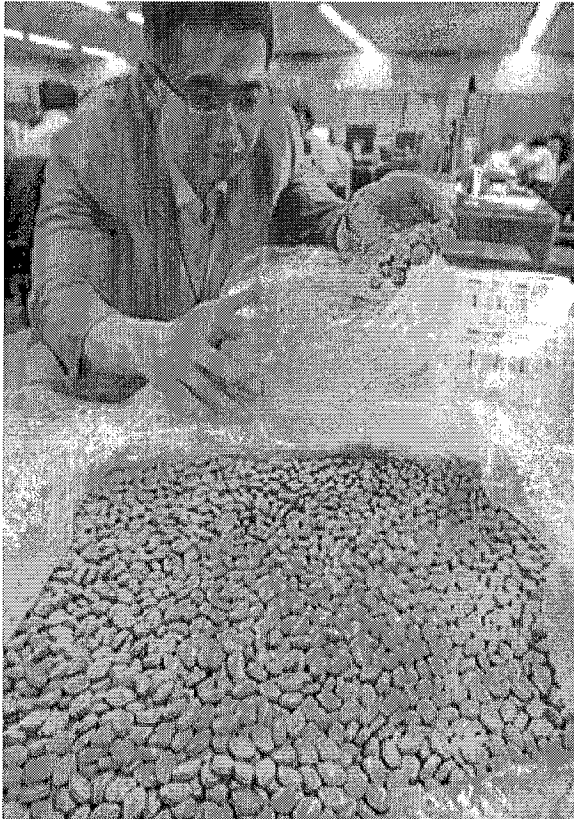
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Los Angeles Times

SPAMMERS ARE MAKING REAL MONEY ON FAKE DRUGS

Cyber criminals see profit and growth potential in shipping counterfeit pharmaceuticals, a study finds.

By Joseph Menn
Los Angeles Times Staff Writer
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Fake Viagra pills like these seized in Seoul in May are a popular item for sale via Internet spam, according to a study by a top security researcher.

Cyber-crime pays. But selling counterfeit drugs apparently pays better.

Some of the world's most prolific spammers used to tout products for a few pennies per million e-mails or con consumers into forking over credit card information.

But these groups have found that the most profit and growth potential lies in actually shipping the fake Viagra and other products they're hawking, according to a study scheduled for release today by a top security researcher.

For consumers, the evolution means that what had been an annoyance and a drag on productivity will get worse.

The new commercial operations use the same combination of cutting-edge technology and best practices, including customer service and supply-chain management, that have brought riches to Amazon.com Inc.

and Dell Inc.

The perpetrators "are what I call the Bill Gateses of cyber-crime," said Pat Peterson, a security researcher at Cisco Systems Inc.

Peterson has spent much of the last year and a half investigating the spam sent by Storm, a piece of malicious software known as a Trojan horse that turns ordinary PCs into spam-spewing robots.

"Gates succeeded not because he was smart, a great engineer or a good businessman, but because he had all of those qualities and an innovative entrepreneurial spirit as well," Peterson said. "That's what we see here."

In the study, Peterson links the Storm system to a Russian drug maker called GlavMed, which uses factories in India and China to churn out knockoffs of Viagra and other popular drugs. GlavMed didn't respond to an interview request.

Cyber-criminals have learned not only how to outwit the computer-security industry, but how to become self-sustaining businesses with substantial budgets for researching and developing new ways to deliver their merchandise.

"There are real products being sold and big money being made," said Joe Stewart, a researcher at network security firm SecureWorks. "It seems unreal that they can get away with it, but they do."

Security firm MessageLabs Inc. estimates that spam already comprises three-quarters of all e-mail. And an estimated 1 in 6 Internet-connected personal computers has been infected by programs that turn them into zombie armies of spam-senders.

Organized crime is exploiting software flaws and human curiosity to increase those numbers. For example, Storm, which emerged last year, uses a wide range of tricks to get users to download it. Instead of including suspicious-looking attachments, Storm sends e-mail with links to fake holiday cards and YouTube videos.

When visited, those websites look for security holes in the computer user's Web browser and other programs. If they don't find those holes, they ask the user to download a purported video player or other software that infects his or her machine with the Trojan horse.

To make the e-mails more enticing, Storm uses headings related to current events, such as the winter storm in Europe that inspired researchers to give the enterprise its name.

Computer owners usually don't notice that their machines have been turned into pawns of the spam operation, because the PC is pressed into service only sporadically.

Although some security firms say Storm infected tens of millions of machines, Peterson thinks it peaked in July at 1.4 million.

Stewart said Storm was the fifth-most pervasive zombie system of the moment. All told, he said, the top 11 have more than 1 million captive computers and can send 60 billion pieces of spam daily.

Storm's genius for infecting new hosts is just one of the technical innovations that make it what Peterson said was the most effective Trojan to date. But the economics behind Storm make it stand out from other malicious programs.

A few years ago, buying something from a spammer usually meant that a crook would charge your credit card and resell the account number to other criminals. The goods never arrived.

But, as they say in Silicon Valley, that business model didn't scale. To charge lots of credit cards, one needs a merchant account. And that usually means a verifiable physical address, various forms of documentation -- and no long list of demands for refunds.

The brains behind Storm simply decided to find a more legitimate business. According to Peterson, they hooked up with GlavMed, which supplies counterfeit drugs, and SpamIt, GlavMed's covert system for processing orders over the Web.

Peterson said his smoking gun was "broken" pieces of spam sent by Storm-infected computers that referred to SpamIt's internal systems.

About 80% of that spam now touts drugs from such websites as MyCanadianPharmacy.com, which Peterson estimates takes in \$150 million each year. Most of those who place orders will get pills from Mumbai, India, or Shanghai that contain 100% to 110% of the advertised dose of the active ingredient.

Exactly who is in charge of Storm remains a mystery.

The few arrests and limited improvements in anti-virus software might have taught the remaining practitioners whom and what to avoid.

Just like the overuse of antibiotics can produce more resistant strains of human viruses, Peterson said, "We've generated these super-gangs in Eastern Europe that have moved way outside the jurisdiction of any law enforcement. They have created a criminal ecosystem that completely isolates them from the security community."

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The Counterfeiting Superhighway

www.eaasm.eu

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Ian Banks

Robin Hood was a very popular, if mythical man. Especially with the poor to whom he gave after robbing the rich. Non Governmental Organisations (NGOs) are always on the look out for such people, not least because of the often paucity of tangible support for their work from member state governments. At the same time, health services in developing nations struggle to meet the cost of new drugs replacing less effective medical treatments. Temptation is always there to seek medication outside the 'conventional' system especially if it is cheaper, embarrassment free and comes with exorbitant claims for efficacy.

Simply defending the rich (pharmaceutical companies) against access to cheap drugs by the poor (underdog people) is not sufficient grounds for addressing the menace of counterfeit drugs, particularly on the internet. Compared to the average person and even some countries' healthcare providers, the pharmaceutical industry is indeed prosperous. They would argue this is vital to secure research into safe, effective new drugs that many, if not all governments appear unwilling to fund. Unfortunately this is no comfort to someone desperate for an anti-viral, anti-cancer or for instance, anti-erectile dysfunction (ED) medicine. It is upon these vulnerable people that the great counterfeit con is perpetrated. Their need is driving them into the arms of counterfeiters, who have no interest whatsoever in the safety or efficacy of their greasy products. Worse still, it can deprive people from definitive diagnosis. Purchasing counterfeit ED drugs via the internet may avoid embarrassing questions and examination from a physician but deprives the patient of expert advice on the underlying conditions causing ED in the first place. These include diabetes, hypertension and lipid disorders, perhaps the greatest combined undiagnosed killers of men.

This report is definitive evidence that governments, healthcare providers and especially NGOs need to wake up to the threat from counterfeit medicines. Pushers of these products are hoods but not of the Robin variety. Stealing from the poor to give to themselves gives an even greater myth for patient care.



Ian Banks
President, European Men's Health Forum

Forewords

Jim Thomson

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The internet has the power to be the greatest single force for good in history, the capacity to enable each of us to learn about people, places and events that were previously unimaginable. Daily, billions of people use this remarkable resource to communicate, conduct business, buy and sell goods and services. It's hard to remember what daily life was like before the internet and equally to imagine life without it. However, surely, with this capacity comes responsibility.

How many of us would routinely invite fraudsters, thieves, pornographers, paedophiles, criminal gangs, terrorists and the like, into our homes? All of these inhabit the dark recesses of the internet and, every time we log on, we risk coming across them. While conducting *The Counterfeiting Superhighway* research, the EAASM encountered some extremely unscrupulous internet traders. To my mind, they are among the worst type of online predator, and are totally uncaring for their target. They don't spare a second's thought for the health and welfare of their 'customer'. They don't care if the customer (potentially every one of us) lives or dies, gets well or manages an illness. These criminals (and that's exactly what they are) are the manufacturers and purveyors of counterfeit medicines, and their activities pose a significant global threat to public health today.

The purpose of this report is not to frighten vulnerable patients. It is to raise awareness and speed the day when the internet is a safe place for the collective good of humanity, and not a free-for-all for criminals. To do that, we need to engage not only with patients and regulators, but with all those global stakeholders in the business of e-commerce, whose actions or inactions add a veneer of legitimacy to this heinous trade. That is our mission and that is why we undertook this ground-breaking research, the second major investigation in the short life of the EAASM. Failure is not an option because the internet is here to stay and those of us in a position to secure it must do so, not just to protect ourselves, but also our children and future generations. The EAASM is not in the business of doing nothing and I commend this report to you. It is shocking and the story it tells demands action. What other choice do we have?



Jim Thomson
Chair, EAASM

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Executive summary

This report has been written with one goal in mind — to raise public awareness of the inherent dangers of purchasing prescription-only medicines (POMs) via the internet. Registered online pharmacies can provide advice and offer convenient access to healthcare products for people who are perhaps elderly, disabled or who live in remote areas or work long/unsociable hours. 'So, why is buying medicine online such a dangerous practice?' one might ask — after all, the internet is the modern, fast, easy and cheap access route to all our daily needs, from food to clothes, music and even car insurance. However, after reading this report and the research herein, you may think twice before putting your life in the hands of unscrupulous internet traders who have no qualms about providing substandard, fake and possibly lethal medicines online.

This objective of this report was to clarify the likelihood of medicines purchased online being counterfeit, substandard or otherwise illegal, and to develop recommendations that will protect patients and consumers from the potentially lethal outcomes of access to these products. Following an in-depth analysis of over one hundred online pharmacies, commonly purchased POMs were ordered online. Expert visual analysis over 30 purchased medicines concluded that an alarming 62% were substandard or counterfeit. Add to this the danger of obtaining POMs (be they genuine or fake) without any medical assessment or guidance — as was possible with over 90% of the online pharmacies investigated — and the very real threat of internet pharmacies becomes clear.

Furthermore, upon laboratory analysis, it was found that when buying POMs from unregulated internet pharmacies, you have a **three in five** chance of receiving a substandard, counterfeit or unapproved medicine. Finally, the Conclusions and Recommendations section of this report calls for all stakeholders to assume responsibility and take action on this issue.

Introduction

The European Alliance for Access to Safe Medicines (EAASM) is a pan-European, patient safety initiative committed to promoting the exclusion of counterfeit and substandard medicines from the supply chain. As a cross-section patient organisation we strive to engage with all relevant stakeholders to ensure that European patient safety is guaranteed.

The EAASM aims to:

- ★ raise public awareness of the dangers of counterfeit and substandard medicines
- ★ create a call for action for improved legislation, enforcement and patients' rights to safe medicines
- ★ input into existing anti-counterfeiting initiatives where appropriate
- ★ contribute to European health literacy.

Counterfeit medicines reach patients in a number of ways. There has been an explosion in the number of counterfeit medicines in recent years, which is reflected by the intensifying rate at which fake and substandard products are making their way into the hands of European patients. The two most obvious and worrying are through infiltration into the European distribution system, and via the internet.

The Counterfeiting Superhighway is the second in a series of research reports conducted by the EAASM which aim to highlight the risks of counterfeit medicines and the growing danger to European patients' safety. This report sees the EAASM focussing its attention on a great global threat to patients; internet drug-sellers.

Background

What is a counterfeit medicine?

A medicine is counterfeit when it is deliberately and fraudulently mislabelled with respect to its identity, history and/or source. This means that the box, tablet pack, patient information leaflet or any other packaging, labelling and documentation associated with it may display the wrong name or product information, be printed in the wrong language or be missing security stickers or holograms.

If there is anything suspicious about a medicine or if it is different from the original product in terms of presentation (colour, taste, crumbliness, shape, size, stamped logos etc) or packaging (language, medicine names, indicated dose strength, printing etc) then it may be a counterfeit product.

Because counterfeit medicines are frequently substandard, poor quality copies of original products, they can be very dangerous. Due to their altered chemical composition, they may contain too little or too much active ingredient as well as other non-standard chemicals. However, medicines can still be counterfeit even if they started life as original products, in the same way that a stolen BMW may still be considered a BMW. Put simply, a counterfeit medicine can be chemically identical to the original product, despite the fact that it is indeed counterfeit, in the same way that a car made originally by BMW becomes illegal if it is sold with the wrong licence plates or false documentation.

Why are counterfeit medicines dangerous?

Counterfeit medicines are potentially lethal because they frequently contain incorrect components and/or the wrong doses of active ingredients. A medicine not only contains the active therapeutic components but also several other ingredients which act to stabilise and preserve it, as well as to help it break down correctly inside the body. Counterfeit medicines may contain:

- ★ an incorrect amount of active ingredient (too little can be as dangerous as too much)
- ★ a wrong active ingredient
- ★ no active ingredient at all
- ★ toxic and/or other non-medical components (eg road paint, floor wax, shoe polish, talcum powder, chalk)
- ★ the correct ingredients, but fake packaging and documentation.²

People can deteriorate rapidly, irreversibly and in some cases will die as a result of taking these 'weak' counterfeit medicines. When a counterfeit medicine has too much active ingredient, the result is essentially the same as overdosing. Regardless of what the medicine was supposed to do, too much active ingredient will harm or even kill people very quickly.

Although the taker may not die immediately, it is likely that they will be left with serious and long-term health problems.

Ultimately, counterfeit medicines are dangerous because they satisfy few, if any, of the stringent licensing requirements which exist to protect patients. Unless a medicine is a genuine product from the pharmaceutical manufacturer, anyone taking it puts themselves at a high risk of harm, and even death.

What types of medicines are counterfeited?

Generally speaking, counterfeiters are attracted to two types of medicine: those which are used in high numbers and those which have a high monetary value. In developed markets such as many of those in Europe, the products most commonly faked are those which are often referred to as 'lifestyle' medicines, such as those for erectile dysfunction, hair loss and weight management. These are medicines people may buy online because they do not wish to discuss the problem with a doctor, or in fact anybody else.

In a shocking development, it was discovered relatively recently that fake versions of lifesaving prescription medicines for cancer and serious cardiovascular diseases are also being sold to consumers online.³ New counterfeits are being discovered all the time, rendering the internet a highly treacherous place to buy medicines.

Both branded and generic medicines can be counterfeit.⁴ This means that newer medicines whose branded names are protected by a patent (eg, Viagra) can be faked, as can medicines which are referred to by a generic, chemical name (eg, sildenafil citrate).

Who makes counterfeit medicines?

Medicine counterfeiting is a worldwide criminal activity undertaken by a range of corrupt operators. They do it because it is a highly lucrative activity, costs are kept low by selling products online, and because there is a low risk of getting caught.

Counterfeit medicines can be made and distributed by just a few people running a small-scale operation from a garage or commercial building. At the other end of the scale, multinational criminal networks collaborate in the high-volume production of counterfeit medicines (usually in Central and Eastern countries such as China and India) and they are distributed around the globe.

There is evidence to show that counterfeiters have used Oceania and the Islands of the Bahamas as an intermediate destination for fake medicines sent from China and the Middle East. From there, the products are distributed around Europe and other regions having been sold via online traders masquerading as legitimate pharmacies based in Europe, the US and Canada.³ Many counterfeit medicines are made in filthy back street 'laboratories' in developing countries. These contaminated rooms are a far cry from the spotless, hygienic laboratory facilities and regulated

manufacturing processes used by pharmaceutical companies.

Some medicines sold fraudulently in Europe may have been rejected originally by pharmaceutical companies due to quality control or related issues. These medicines are rightly disposed of, though it is not impossible for criminals to find them and try to sell them online. Other medicines may be

thrown away because they fall out of date, but these too can sometimes reappear, perhaps in new (fake) boxes, via internet-order deliveries.

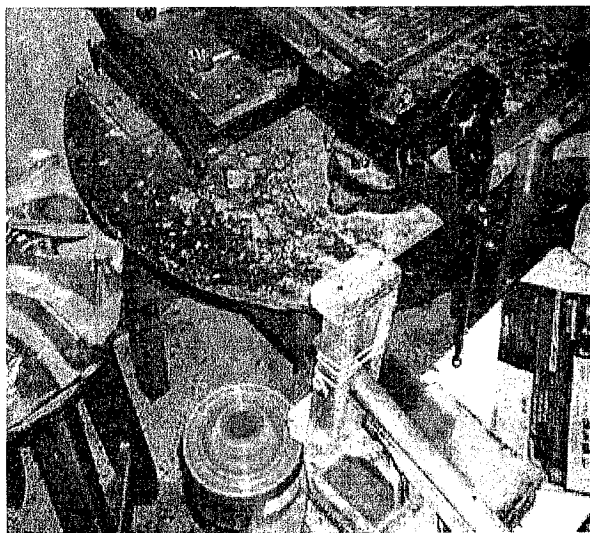
Another key issue is that some medicines require refrigeration or other specific

environmental conditions during transport and storage. If stored incorrectly their effectiveness can be reduced, rendering them useless or even dangerous. It is highly unlikely that medical products are handled correctly by criminal distributors. Counterfeit medicines have been discovered hidden during transportation within soft toys, large carriers bags and cardboard boxes – a world away from the strictly regulated and sterile conditions required for licensed medicines.

How significant a problem is medicine fraud and counterfeiting?

It is fundamentally impossible to declare the true magnitude of medicine counterfeiting on a global scale due to its clandestine nature. Counterfeit medicines are shipped covertly across a range of international jurisdictions and frequently traded via unofficial and uncontrolled websites. We know however that the industry is growing rapidly each year because reports of suspicious packages and seizures of illicit goods are increasing continually.

The latest intelligence available on the incursion of counterfeit medicines reveals a worrying trend: the volume of counterfeit medicines seized in Europe has increased exponentially in recent years, with more than 500,000 products discovered in 2005 – twice the level found in 2004. In 2006, this figure was reported to have increased by more than five times, to 2.7 million.⁵ This explosion continued throughout 2007 and is rising all the time. The Center for Medicine in the Public Interest, based in the US, predicts that counterfeit medicine sales will reach approximately €55.5bn globally by 2010 – an increase of more than 90% over just five years (from 2005).⁶



A 'back-street laboratory'

According to the World Health Organization:

- ★ 50% of medicines purchased over the internet from sites that conceal their physical address are counterfeit
- ★ 10% of medicines sold in developing countries are fakes
- ★ 1% of medicines sold in developed markets, such as the European Union, are counterfeit.⁴

While it is generally suspected that the 1% figure in the EU is now much higher, it is still highly significant. Even the 1% figure would mean that, last year alone, over 7 million UK and 16 million German prescriptions may have been filled with counterfeit medicines.^{7,8}

Are certain countries more at risk than others?

This corrupt practice is more acute in Asian countries with developing economies, where it is thought that the majority of counterfeit medicines are produced, such as China, India, Russia and the Philippines. Markets such as West Africa and South America are also vulnerable, as counterfeiters are attracted to regions with weaker regulatory and legal control, where the supply of medicines is poor or where prices are generally unaffordable. It is estimated that as many as one in three medicines in such markets is counterfeit.⁴

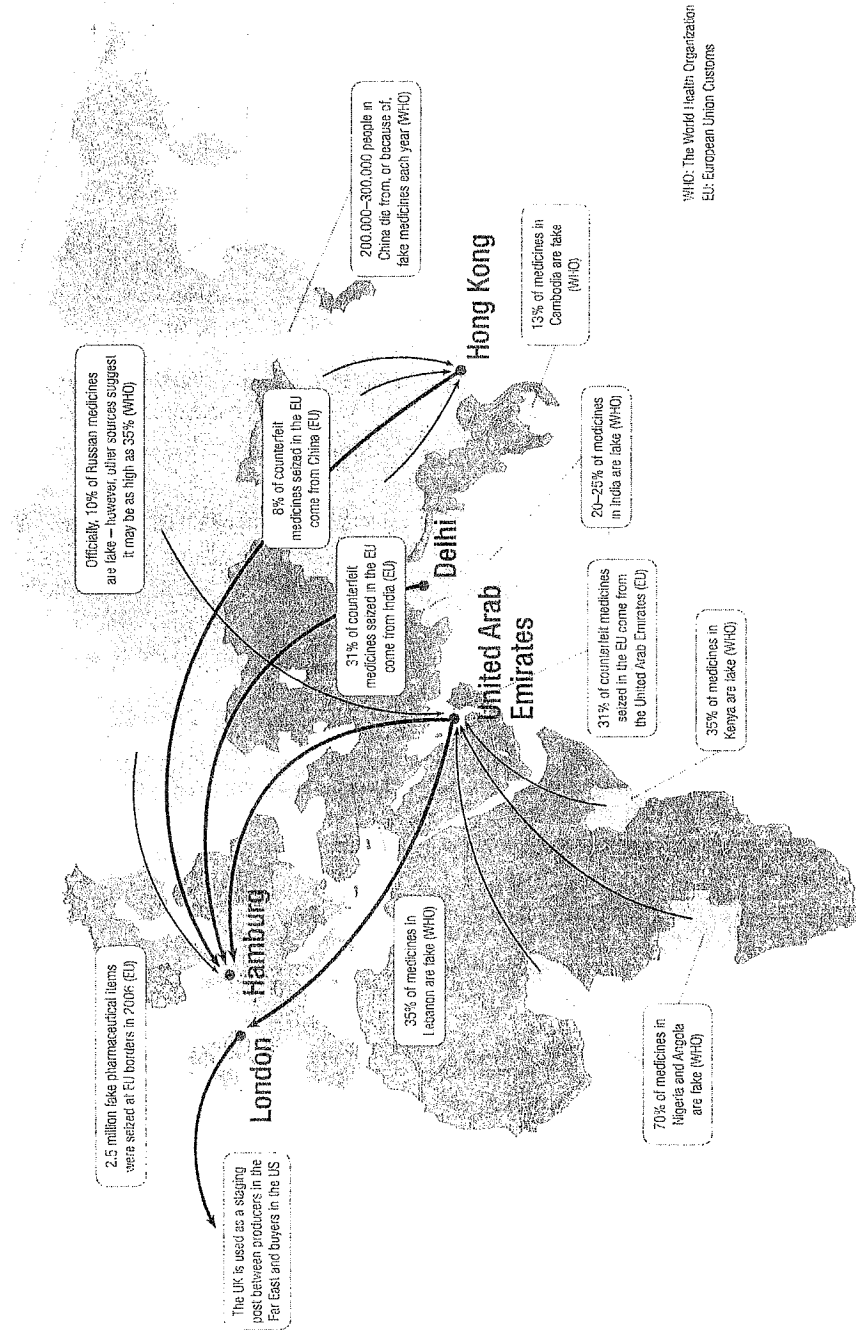
The risks to developed European countries (where regulatory oversight is more stringent) are increasing rapidly due to the internet and its ability to facilitate cross-border trade. The internet, now fairly ubiquitous in Europe though poorly regulated with regard to buying medicines, represents a major loophole through which counterfeit medicines can reach consumers. People use the internet increasingly to buy a variety of goods, and medicine counterfeiters are taking advantage



of an assumption that in return for payment people will be supplied with authentic, licensed products.

Unarguably, medicine counterfeiting is a significant public health challenge requiring the urgent attention of international regulators and lawmakers, pharmaceutical companies, healthcare systems, pharmacists and – most importantly – patients and online customers.

Counterfeit medicines trade: a global threat



Online pharmacies – The counterfeiting superhighway

13

What is an online pharmacy?

A legitimate online pharmacy is essentially the same as any other website through which consumers can purchase products, but in this case, medicines and medical devices. When used appropriately, legitimate online pharmacies offer a convenient, discreet and fast delivery service for medicines and healthcare products. Prices are typically lower compared with high street pharmacists and items are delivered direct to your door.

Registered online pharmacies can provide convenient access to healthcare products and advice for people who are perhaps elderly, disabled or who live in remote areas or work long/unsociable hours. They offer significant advantages for people who cannot easily travel to a medical centre or high street pharmacy.

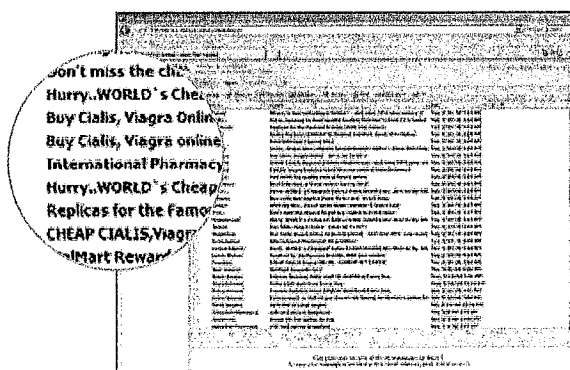
Online pharmacies will ask you for registration information and credit card details for payment. Where prescription-only medicines are requested, buyers must also provide an authorised prescription, usually by post, before the products can be dispatched. Without this, it is illegal for any medicines supplier to sell or provide prescription medicines.

How do unscrupulous online medicine sellers find customers?

Everyone in Europe with an email account will almost certainly have received 'spam' messages providing them with opportunities to buy medicines online. Most of the medicines for sale through these avenues are likely to be counterfeits.

Given their nature and value it is unsurprising that the most popular medicines for sale online purport to enhance sexual performance. Opportunities to buy Viagra, Cialis and Levitra, for example, appear frequently in email spam. For the majority of recipients these emails are merely an annoyance. However, as there are billions of medicine-related spam emails sent everyday even if a tiny proportion of people bought medicines online as a result this translates into many tens of thousands of counterfeit medicine sales each day.

Search engines are the chief method by which distributors of illegal and counterfeit medicines find customers, and much of the explosive growth in sales of these medicines has been driven by unauthorised internet pharmacies who market their wares directly to consumers online.



'billions of medicine-related spam emails sent everyday'

What are the risks?

Quick, convenient trading afforded by the internet has seen many legitimate online pharmacies open for business in the past few years. However the internet has also created an opportunity for web-based suppliers with no professional qualifications or healthcare expertise to deceive unknowing consumers into buying dangerous, illegal and/or counterfeit products. The vast majority of online pharmacies uncovered via search engines, email spam and online supermarkets are untrustworthy and will readily provide online buyers in Europe with illegal, substandard and/or counterfeit medicines. One of the most concerning aspects from a patient safety perspective is that the majority of websites evaluated appear to be sufficiently well written and presented as to easily, and wrongfully, gain the confidence of unknowing consumers.

Many of the illegal websites sell prescription medicines, or unsafe counterfeit versions, directly to members of the public without a valid prescription or consultation with a healthcare professional. This is the most dangerous aspect of online medicines trade as it removes patients from the medical consultation system.

Medicine watchdogs all over the world allow the supply of particular products on a prescription-only basis (ie, requiring an authorised prescription from a physician) because it is dangerous to people's health if such medicines are taken without expert consultation. Some may interact harmfully with other prescribed medicines while others may require close monitoring to ensure the dose is appropriate. Moreover, without a physical examination by a qualified doctor or other healthcare professional, the medication you receive could worsen an underlying, as yet undiagnosed condition.

Some illegal websites may offer users an "online consultation", however this is often nothing more than a simple questionnaire and

is not a valid means to obtain prescription-only medicines from an online supplier. It is highly likely that such websites will deliver ineffective, unapproved and/or bogus medicines which will harm – and possibly kill – people.

There has been an increase in 'self-prescribing culture', particularly for medicines used to treat conditions such as; sexual dysfunction, weight loss, hair loss etc. By ordering medicines online without a prescription, people remove themselves from the protection and care of their national health service. For example, a consumer who buys Cialis over the internet because they are too embarrassed to see a doctor about erectile problems not only risks buying a counterfeit medicine, but the lack of a proper medical diagnosis means that any other health conditions remain undetected. Erectile dysfunction, for example, can be a consequence of serious cardiovascular diseases such as high blood pressure and diabetes. Without a doctor's diagnosis, these diseases may not get treated and could lead to heart attacks, strokes and blindness over time. Additionally, without a physician checking their medical and prescription history, harmful interactions could occur with other medications which people may be taking.

Isn't the internet regulated to protect buyers?

At present the internet is weakly regulated with regard to the purchase of medicines. Controls and safeguards relating to internet based commercial operations do exist, however consumers are neither automatically prohibited from buying illegal and/or counterfeit medicines, nor are they protected from the ill effects of unlawful online medicine sales. Because of the anonymity and poorly regulated nature of the internet, there is a low risk of perpetrators getting caught and their operations being shut down.

Why do people buy medicines online?

Some sections of society such as the elderly, disabled and people unable to visit a high street pharmacist during normal working hours may choose to buy their medicines from a legitimate, registered online pharmacy. However, other people may source medicines online because:

- ★ of the speed and convenience
- ★ they are too embarrassed to discuss their condition with a doctor, nurse, pharmacist or other healthcare professional
- ★ they do not want their family or employer/authorities to find out about their condition
- ★ they fear that a doctor might be reluctant to prescribe them a particular medicine
- ★ they believe that the costs are lower.

Despite the dangers, the purchase of medicines online has quickly become a comfortable option for busy or anxious buyers using the internet as a tool to side-step the normal health service processes.

The relative anonymity encourages people to access advice and products for which they would be reluctant to ask their healthcare provider or pharmacist.

Online pharmacy is safe and acceptable for patients with a genuine need for a delivery service and, crucially, who are able to recognise a legitimate, registered supplier. For a large and increasing number of poorly educated or misguided people, however, buying prescription medicines over the internet is a hazardous practice which allows illegal, substandard and counterfeit products into their country. Medicines bought via illegal websites are at best poor quality and ineffective, and at worst lethal.

While endeavours to tackle the sources of fake internet pharmacies have been stepped up significantly by authorities in Europe, it is feared that the counterfeits market is growing so rapidly that security forces are struggling to curtail it.

While authorities have had some successes in closing down illegal sites and prosecuting those behind the businesses, it is a significant challenge to find these nameless, shadowy online operators. Illegitimate internet pharmacies

selling prescription medicines open and close on a daily basis, while a single outfit masquerading as a registered business may have many URLs or web addresses. Therefore, tracking the movement of products and finding the 'brains' behind counterfeit medicine sales requires sustained, intricate and often covert operations.

Are there any safeguards in place?

Several associations and other representative bodies have introduced (or are currently testing) schemes which help consumers distinguish genuine internet pharmacies from illegal online medicine traders. These initiatives go some way to protecting consumers, though it is recognised that counterfeiters and unscrupulous online medicine traders will attempt to get around whatever security measures are put in place. It is therefore a continual challenge.



RPSGB online pharmacy logo – provided to registered pharmacies



The VIPPS seal of approval

The Royal Pharmaceutical Society of Great Britain

The Royal Pharmaceutical Society of Great Britain (RPSGB) has created an internet pharmacy logo which is displayed on the front page of participating online pharmacy sites. By clicking on the logo, visitors are linked to a page on the RPSGB website where they can make checks to assess authenticity of what claims to be a bona fide registered online pharmacy.

Registered pharmacies are given a unique number which appears within the logo. When the logo is clicked, this number should match the records presented on the RPSGB link. As all legitimate online pharmacies should also be registered with a 'bricks and mortar' building (ie, a physical address) this too can be checked on the RPSGB link.

While the 'approval logo' attempts to create some kind of safeguard, the RPSGB acknowledges the risk that criminals could copy their logo and apply it to the front pages of illegal internet medicine traders. There may

also be the possibility that some will attempt to recreate the 'link' to the list of registered online pharmacies. While this initiative is a step in the right direction the RPSGB recommends that web users use it in combination with other security measures, as follows:

- ★ check the registration status of the pharmacist
- ★ look for the name and physical address of the pharmacy operating the website (all legitimate internet pharmacies should display a bricks and mortar address)
- ★ avoid ALL online pharmacies which offer to supply prescription-only medicines without a prescription
- ★ observe whether or not you are asked questions before purchasing your medicines (registered pharmacies are required to perform a consultation – even online – with a health professional).

Verified Internet Pharmacy Practice Sites (VIPPS)

The Verified Internet Pharmacy Practice Sites (VIPPS) seal of approval is an international system, operating in parts of the US, Canada, South Africa and Australia, which aims to protect online consumers in a similar way to the RPSGB initiative. To be VIPPS accredited, a pharmacy must comply with the licensing and inspection requirements of their home state as well as any to which they dispense pharmaceutical products. In addition, online pharmacies must also prove their compliance with specific requirements such as patient rights to privacy, authentication and security of prescription orders, adherence to a recognised quality assurance policy and provision of a meaningful consultation between patients and pharmacists.

When clicking the VIPPS logo, consumers are linked to the National Association of Boards of Pharmacy (NABP) VIPPS site where information is stored which helps identify genuine online pharmacies from rogue traders. There is also the opportunity for consumers to 'Report-a-site'

if they believe an internet pharmacy is wrongly claiming to be a legitimate, trustworthy business. Unfortunately, counterfeiters may also copy this logo, as mentioned above.

PharmacyChecker

PharmacyChecker is a free-to-consumer online service which produces reports on the credentials, prices and customer feedback of online pharmacies. It is designed to help a variety of individuals and groups identify the most reputable and trustworthy businesses by publishing ratings, profiles and cost comparisons on its website (www.pharmacychecker.com). The service focuses chiefly on US and Canadian trade, though for Americans seeking medicines that are unavailable in their home market it will also verify the licences of European and other 'foreign' pharmacies.

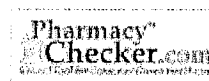
PharmacyChecker evaluates policies, procedures, contact details and licences for many online pharmacies. It also publishes a list containing the web addresses and 'business names' of what it considers to be disreputable, dishonest and/or illegal online medicine trade sites. The existence of any and all of these user protection and security assessment services are testament to the threat posed to consumers seeking to buy medicines – prescription-only products in particular – online.

What are the main issues for European authorities in tackling illegal online pharmacies?

While the unregulated online trade of medicines is a back door left ajar for counterfeiters to weasel their dangerous, illicit wares into the hands of ingenuous online customers, the key issue is one of fake identity, and fraud. Websites masquerading as legitimate online

pharmacies are run by criminals trying, first and foremost, to commit medicine fraud.

Many of these illegally traded products may also be counterfeit, and hence do significant harm – which can even result in death – to those who ingest them. This means that any party in a position to protect the European patient must do so immediately and proactively. This is acknowledged by a growing number of European medicines authorities and lawmakers.



*Pharmacy Checker
produces reports on
online pharmacies*

United Kingdom

The UK is a popular transit point for counterfeiters (UK postmarks add credibility to medicine packages) as well as a popular end destination for fake products. In November 2007, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) organised a conference in London to introduce its first anti-counterfeiting strategy (2007–2010) to the international pharmaceutical community. By July 2007, the agency had issued five separate alerts relating to counterfeit medicines entering the UK market. As well as 'lifestyle' medicines, these included anti-cancer medicines, schizophrenia therapies and life-saving cardiovascular medicines. In April 2008, the MHRA received warnings from overseas authorities regarding several products being marketed as dietary supplements, or 'herbal Viagra', for the treatment of erectile dysfunction. Many were found to contain prescription-only medicines and were sold over the internet.

Germany

An alarming number of people in Germany buy prescription-only medicines online without an authorised prescription. In order to help consumers avoid buying illegal, substandard or counterfeit products, the German Federal Ministry of Health recommends that people consult their health insurance funds, which are able to identify legitimate online pharmacies and explain how to claim refunds on medicines sent by mail. The Ministry also publishes useful advice on 'Medicines and the Internet' on its website (www.bmg.bund.de).

The Counterfeiting Superhighway research

Buying medicines over the internet dramatically increases the risk of exposure to fraudulent, unlicensed and potentially lethal counterfeit products, and this report aims to highlight the dangers to consumers. Presented here are the findings from new research into the health risks posed by pharmacies trading on the internet, the world's largest unregulated market. The objectives of this work are to clarify the likelihood of medicines purchased online being counterfeit, substandard or otherwise illegal, and to develop recommendations that will protect patients and consumers from the potentially lethal outcomes of access to these products.

This research answers two key questions:

- 1 What proportion of internet pharmacies, as sampled, selling prescription-only medicines is acting unlawfully?**
- 2 Of the medicines sold by internet pharmacies, what percentage are counterfeit or substandard?**

The answers to these questions will serve not only to highlight the risks to European consumers but will also show how serious those risks are to people buying medicines online without sufficient guidance or knowledge. It is imperative that the extent and grave nature of these dangers are made clear to European patients and consumers buying medicines online.

Phase 1 – Desk research: Finding and inspecting online medicine traders

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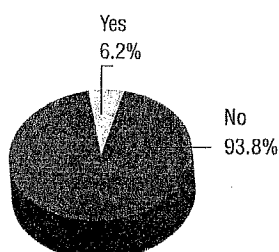
The first phase of the research involved drawing up a list of online pharmacies and performing a thorough analysis of each website. Several different search engines (including Google, AltaVista, MSN and Yahoo!) were used to search for prescription-only medicines based on the following keywords:

- ★ 'online pharmacy'
- ★ 'cheap medicines'
- ★ 'medicines online'
- ★ 'buy [medicine name] online'.

Additionally, email spam filters were deactivated and links from spam messages advertising internet pharmacies and opportunities to purchase medicines online were accessed. Finally, online medicine supermarkets were utilised to source several web-based pharmacies. Over 100 websites identified through these various means were assessed according to a checklist which comprised the key questions any consumer should ask of online medicine traders purporting to be genuine.

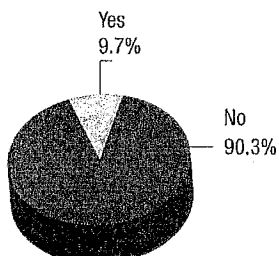
Findings from the online pharmacy assessment can be found in the following charts:

Is there a named, verifiable pharmacist?



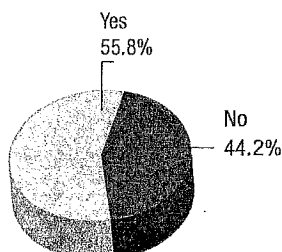
- ★ Nearly 94% of the online pharmacies evaluated did not have a named, verifiable pharmacist to answer questions – this is a dangerous practice as it means that there is no proper medical control or guidance for people purchasing their medicines online.

Is a prescription required for prescription-only medicines?



- ★ More than 90% do not require sight of an authorised prescription in order to sell prescription-only medicines – the health and wellbeing of consumers is placed in severe jeopardy where they can obtain potent medicines without any medical direction or assessment.

Does the website offer bulk discounts?



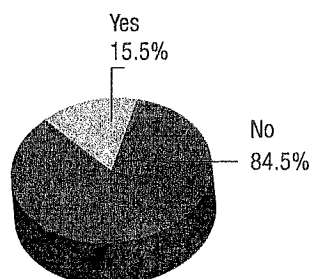
- ★ More than half of the websites offer 'bulk discounts' or 'special deals' on prescription-only medicines – this type of promotion is clearly medically inadvisable and irresponsible and may heighten the risk of serious harm.

The findings from the desk research indicate that the chance of an online medicines trader operating legally and ethically is less than one in 10. This is borne out by the fact that statistically more than nine in 10 internet traders (102 of 116 websites investigated) were willing to sell and dispatch a prescription-only medicine without seeing an authorised prescription to warrant the transaction. This practice is not only illegal but represents a

corrupt manipulation of European consumers who are unaware of the risks. It is profiteering through an appalling lack of regard for human health and wellbeing.

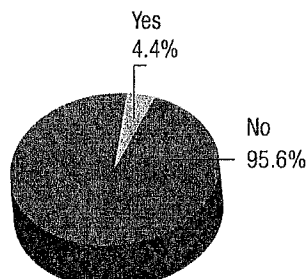
Furthermore, the chances of an online medicines trader existing only 'virtually' – ie, solely online, without a verifiable, traceable physical bricks and mortar address – are greater than 80%. This means that where

Does the pharmacy physically exist?



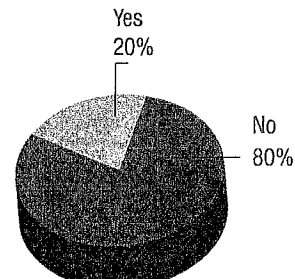
★ More than eight in 10 do not 'physically exist' – in order to comply with the law all online pharmacies must be traceable to a verifiable bricks and mortar address.

Is the pharmacy listed as a legitimate website?



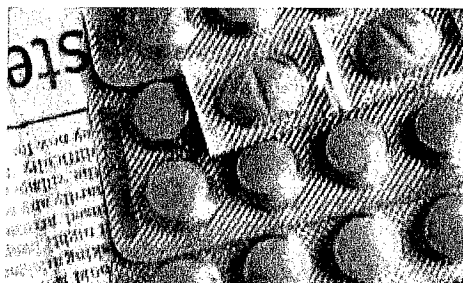
★ Fewer than five in 100 are licensed by a board of pharmacies or appropriate pharmacy listing – this means that they are not bound by any professional, legal or safety regulations.

Is there a 'stamp' of approval by a recognised society?

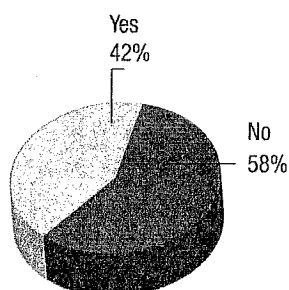


★ One in five online pharmacies evaluated have a 'stamp of approval' from a recognised society or association – however, clicking on these reveals that nearly 86% of them link to a bogus 'approval' web page.

consumers have imprudently purchased medicines over the internet and have subsequently suffered ill effects, or for whom concerns are raised about products received, there is no means by which they – or security services acting on their behalf – can locate the proprietor. Failure to provide a verifiable physical address for online pharmacy trade is also illegal.

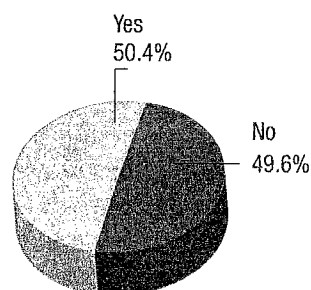


Is there a working telephone number?



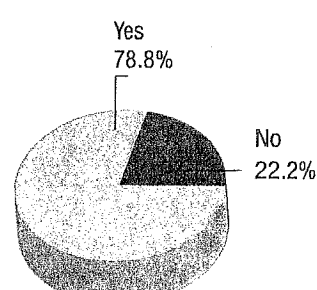
★ The majority do not provide a working telephone number, while approximately just one in six offer an 'online consultation'. With no phone number to call, consumers have nowhere to direct concerns or queries. Many of the online consultations merely comprise a short list of questions which can easily be bypassed, or completed with false information.

Are policy and security policies easy to find?



★ Privacy and security policies were not easy to find in more than half of the operations evaluated – this lack of transparency, preventing consumers from easily finding out how their information will be used, suggests a shadowy, unprofessional business.

Is the website violating intellectual property?



★ Over half of the websites may be violating the intellectual brand property of original pharmaceutical manufacturers by reproducing protected brand images, logos and/or drug names. Where permission to copy or reproduce original branding has not been actively sought and gained, it not only has the effect of duping consumers, but strongly suggests an operation riddled with further illegality.

Phase 2 – Purchasing medicines online

The buying experience

The second stage in the research was to place orders online for a variety of medicines. A credit card (MasterCard) was obtained and designated specifically for this purpose and medicines were ordered to a central location in the UK. Over 36 prescription-only medicines were ordered, comprising two packets each of 18 medicines commonly purchased via the internet. These included medicines indicated to treat neurological disorders, cardiovascular disease, mental health, obesity and erectile dysfunction (Table 1).

This list of medicines was compiled by identifying the top medicines in terms of US sales, as indicated at www.drugs.com/top200.html, and thereby highlighting the most attractive prospects for fraudulent online sales and counterfeiting. Added to this were the results of research undertaken by Jim Thomson, Chairman of the European Alliance for Access to Safe Medicines and an authority on patient safety and counterfeit medicines.

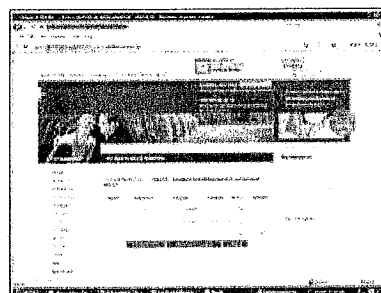
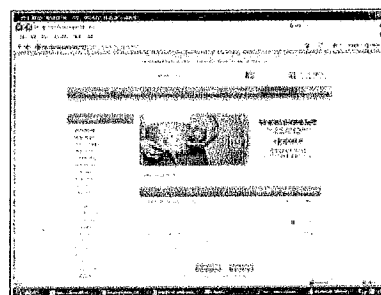
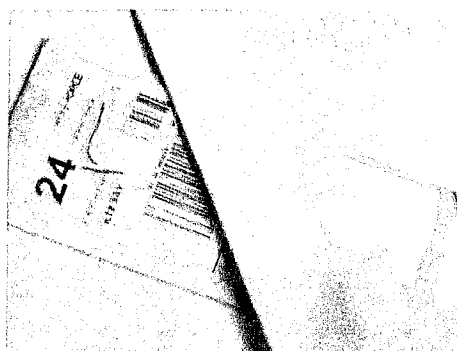
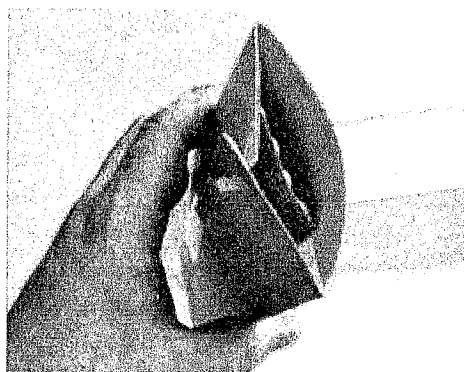


Table 1. Medicines ordered online as part of the Counterfeiting Superhighway research

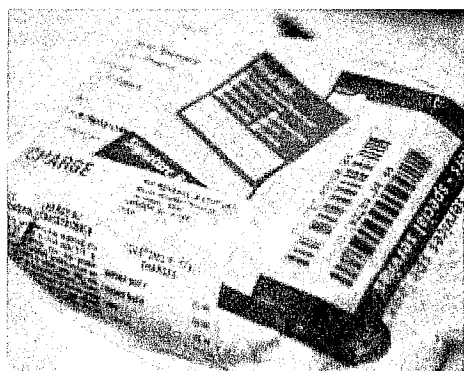
Men's health	Cardiovascular and respiratory	Mental Health	Alzheimer's disease	Other
Cialis (Lilly)	Lipitor (Pfizer)	Zyprexa (Lilly)	Aricept (Pfizer)	Zoton (Wyeth)
Levitra (Bayer-Schering)	Plavix (sanofi-aventis)	Efexor (Wyeth)	Reminyl (Shire)	Reductil (Abbott)
Viagra (Pfizer)	Seretide (GSK)	Risperdal (J&J)		Mirapex (Boehringer-Ingelheim)
Propecia (MSD)	Coversyl (Servier)			
	Micardis (Boehringer-Ingelheim)			
	Spiriva (Boehringer-Ingelheim)			



Finding online traders and placing orders for prescription-only medicines without an authorised prescription was quick, simple and straightforward. During the multiple purchasing processes, few questions were asked and no advice was given. Where the buyer was requested to complete an 'online consultation', it frequently comprised a series of general health-related questions to which answers could be forged or fabricated as there was no apparent protocol in operation to verify answers.



On one occasion only did one of the buyers (a female) receive a phone call from someone seeking to advise that the particular product in question was aimed at the male market; the buyer replied that the medicine was for her husband, which was sufficient to satisfy the trader who subsequently dispatched the medicine.



There were no fundamental barriers or obstacles to purchasing prescription-only medicines online without an authorised prescription. No pharmacists, physicians, nurses or indeed any other type of healthcare professional were involved in the purchasing process to provide direction or guidance in using medicines purchased from an online pharmacy.

Of the medicines ordered, all but two were delivered. Payment was taken for these two outstanding purchases and no indication as to why they were not delivered was ever given. Five of the orders arrived with a few extra, free tablets – these were all pills purporting to be for the treatment of erectile dysfunction.



Phase 3 – Unwrapping and expert analysis

All of the medicines bought online were stored in a fireproof safe until such time as their packages could be opened and inspected by an expert panel. This was done at a bespoke meeting held at the Royal Society of Medicine's premises in London during April 2008. The panel comprised 22 members including representatives from key European patient associations, security specialists, pharmacists, pharmaceutical manufacturer employees, independent security experts, former senior police officers, government liaison personnel and a representative from an international courier and delivery organisation.

The panel of experts were divided into three groups – each group was provided with a number of the products received for examination. Each medicine package was scrutinised visually; some of the packaging alone was alarmingly substandard, with more than one set of medicines merely wrapped in a used newspaper fixed with sticky tape.



The groups evaluated and discussed each package, prompted by the following questions:

- ★ Is the packaging intact?
 - ★ Does the packaging and patient information leaflet appear to be genuine?
 - ★ Are there any unusual logos, patterns or other visual elements?
 - ★ Are the medicines contained safely within blister packs, or other inner packaging?
 - ★ Are there any indications as to where the package originated, or its route of travel to the UK?
 - ★ Do the drugs appear to be consistent with verifiable, genuine examples of the medicine?
 - ★ Overall, do you suspect this to be an illegal, substandard and/or counterfeit product?
- Please explain and discuss your conclusions.

Expert panel – Comments on medicines bought online

It was the opinion of the panel that while several of the medicines bought online were considered highly likely to be substandard and/or counterfeit, the vast majority of typical European consumers would be unable to detect this.

On visual inspection alone, many of the medicines ordered online by the EAASM could have been: genuine, branded products; parallel trade products; genuine generic products; counterfeits, or several combinations thereof. Yet, having received what seemed ostensibly to be what was ordered, the untrained public could readily be expected to consume most, if not all, of the products acquired as a result of their internet transaction. From their expert visual examination of the products, however, the panel identified several issues representing potential dangers:

Packaging

- ★ Some products were presented in the 'wrong' packaging: this included incorrect or poorly copied manufacturer or product logos; unorthodox box size, or a container holding tablets presented in obscure blister pack arrangements.
- ★ A few of the products were presented merely as loose tablets wrapped inside several sheets of newspaper, while others were delivered in envelopes or paper folded over to form an insecure, make-shift packet. One delivery was simply an envelope containing some loose, unidentified tablets inside a small transparent plastic bag.

The packages could also be categorised approximately into two groups, according to the efforts undertaken by the vendor to present the medicines as genuine. In more than 50% of cases the packaging suggested scant efforts to present the contents as authentic, unadulterated medicines; the most notable cases being tablets wrapped in a copy of the Mumbai Daily News, with some medicines presented loose within dirty wrappers. At the other end of this scale, products were delivered in seemingly authentic boxes accompanied by patient information leaflets in good condition and ostensibly 'trustworthy' blister packs.

Patient information leaflet

- ★ 50% of the medicines bought online were presented without a patient information leaflet (PIL) – a consumer purchasing these products would have no guidance on how to take the medicine and what might happen if they did (eg, dose and frequency, side effects, contra-indications, interaction with alcohol or other medications etc). Some medicines provided guidance which merely stated, 'take when needed'.

Blister packs

- ★ Several of the tablet blister packs were identified clearly as irregular in terms of text, print quality, and quality and number/ layout of tablets by the expert panel.

Figure 1.
Packaging

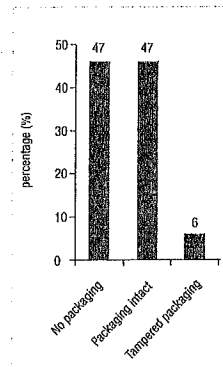


Figure 2.
Patient information
leaflet supplied

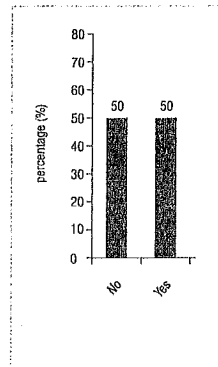


Figure 3.
Patient information
language

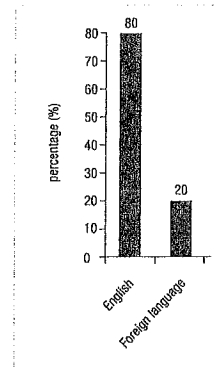
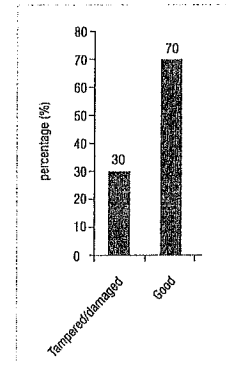


Figure 4.
Condition of
blister pack



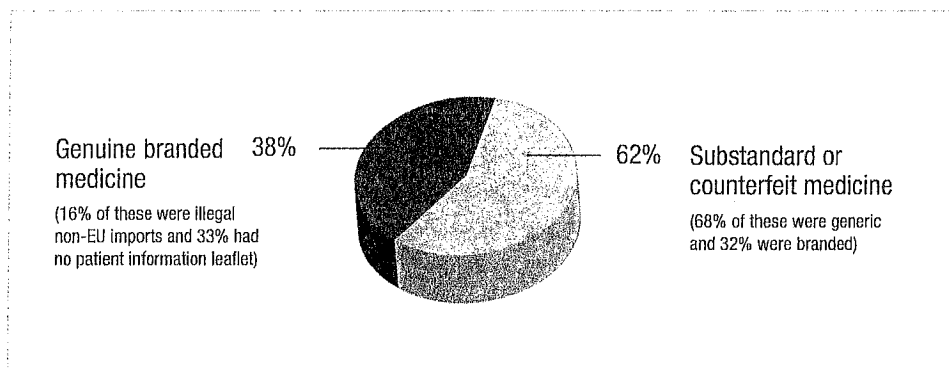
General expert observations

- ★ The details on the packaging and tablet blister packs, as well as the products themselves, were frequently incorrect or suspect, such as:
 - one or more foreign languages printed on the label or box
 - poor English
 - inferior quality of paper and blister pack
 - too much glue on the seals
 - incorrect colour schemes for (either or both) packaging and tablets
 - wrong entity (logo, emblem etc) printed on tablets, several of which were also the wrong shape and size
 - incorrect, or unrecognisable watermarks on leaflets where included.

- ★ Certificates of 'Authenticity' provided with several of the products were deemed to be false, due to suspect printing and presentation.

The notable experience and expertise of this panel meant that members would be expected to identify these irregularities. Despite the conspicuous nature of this deviance from original manufacturers' product, European consumers unacquainted with orthodox medicine packs could not be expected to notice anything amiss in the majority of cases.

Figure 5.
Analysis of prescription-only medicines
bought online



Laboratory analysis

Following the expert scrutiny, the products were sent to their original pharmaceutical manufacturer laboratories (or at least, what should have been their original sources) for chemical analysis. Where this was not possible, the products were analysed using a handheld Raman spectroscopy instrument* which enables field-based identification of counterfeit pharmaceuticals. This analysis was done in order to:

- ★ evaluate authenticity
- ★ assess efficacy/determine the proportion (if any) of active ingredient
- ★ identify medicines containing harmful non-active, or 'filler' ingredients
- ★ check for degradation of the product due to poor storage and/or transport conditions.

Findings of the analyses are described below:

Results of the laboratory analysis indicated that an alarming 62% of the products received were counterfeit, substandard or unapproved generic† medicines. This figure closely reflects the findings of the expert panel during their visual analysis of the medicines. However, for

the general public, it would prove much harder to correctly identify the substandard or counterfeit products. Worryingly, one of the products which the expert panel deemed to be genuine upon visual inspection, was found to be counterfeit upon laboratory analysis.

Whilst 38% of the medicines received were found to be genuine branded medicines, 16% of these were illegal non-EU imports (genuine products, imported into the EU illegally from a non-EU country), and 33% did not have patient information leaflets, which, as has been discussed, is a threat to patients.

In conclusion, if you buy your life-saving, prescription-only medicines via unregulated internet pharmacies, you have a three in five chance of receiving a substandard, counterfeit or unapproved medicine. Of those who are lucky enough to receive a genuine medicine, one in three will not be provided with the essential patient information leaflet – which could result in serious harm to health. Finally, all prescription-only medicines delivered without requiring the sight of a prescription are illegal and are a serious threat to public health.

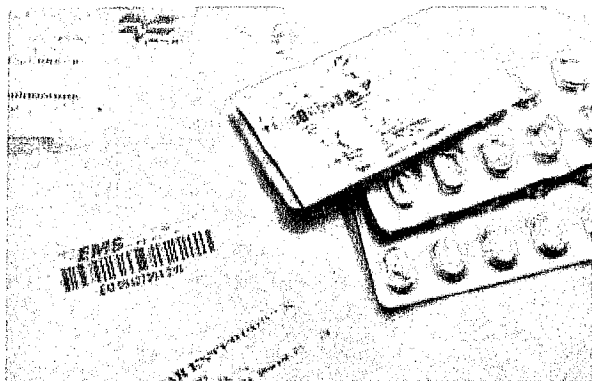
* the EAASM would like to thank Ahura Scientific for the use of their TruScan device

† an unapproved generic medicine has been manufactured by a company who does not have permission from the original developer

Conclusions and recommendations

With just an internet connection and a credit card, medicines that are stringently regulated in Europe and global markets can be bought effortlessly over the Internet. As the results of this research reveal, the actual products delivered to buyers range from genuine — though still illegal — to dangerous substandard copies and illicit counterfeit products. This heinous state of affairs is compounded by the fact that European consumers are neither protected from this criminal practice, nor equipped — or as yet even sufficiently informed — to be able to recognise the unlawful supply of illegitimate, substandard and counterfeit medicines for themselves. At present, online buyers receive no shelter from the threat, and ironically the attraction afforded by deceptive and corrupt online medicine sales.

A tendency to avoid embarrassing or inconvenient visits to a family doctor means that men in Europe are also relatively more likely than women to source medicines online, using their credit card to pay for the products. Due to the 'covert' nature of this procurement, it is also likely that many will not question the safety and efficacy of the products delivered, even in cases where the packaging or condition of the medicines may be manifestly suspect. The same keenness (even a notable sense of relief) in avoiding the regulated healthcare provision may also serve to allay doubts about medicines bought online. Of the medicines sold by internet pharmacies 62% of medicines received were substandard or counterfeit.



Credit cards and internet payment security (or lack of)

Even if one is remarkably lucky to avoid damaging or worsening one's health by taking products bought – albeit unknowingly – from an unscrupulous online pharmacy, a consumer may still fall foul of the growing menace that is credit card and identity fraud. Buying medicines online requires the details of a valid credit card, a key part of which is very often the full name and address of the cardholder. If unprincipled operators are willing to peddle poor quality, illegal and potentially lethal copies of life-saving medicines online, there is a substantial likelihood that they will attempt to sell or use buyers' credit card details – and, hence, online identity – for other illicit activities.

Due to the online presence of credit card processing and merchant account companies, illegitimate, as well as legitimate online pharmacies are able to process most major credit cards, without going through a major high-street bank. This means that consumers' personal banking details could more easily fall into the hands of unscrupulous traders. In view of the covert nature of the trade and

the relative poor regulation of the internet, perhaps it would be above and beyond realistic expectations for finance companies to monitor every single purchase. However, given the explosion in fraudulent and counterfeit medicines in Europe, their danger to human health and the role the internet plays in putting them in consumers' hands, now is unarguably the time for credit card companies to take action and for regulators to look into the workings of credit card processing and merchant account companies.

When people travel abroad and use their credit cards, transactions are often stopped or suspended until they answer some security questions on the telephone (unless they provided advance notice). Why then, when people have already died as a result of taking phoney medicines bought with credit cards from crooked internet traders, should a similar safeguard not be put in place for online pharmacies?

What can be done to stop online medicine fraud?

It has been suggested that companies facilitating online commerce, such as search engines and credit card firms, should be required to prevent the purchase of illegal medicines via the internet.

Services such as Google, Yahoo and MSN – along with other popular internet search engines – could remove web pages from search results advertising counterfeit medicines. This has already proved to be successful in stopping people finding (accidentally or purposefully) websites related to other crooked or unprincipled interests and activities, such as child pornography for instance.

If the same level of censorship were applied to all unregistered online pharmacies not only would all existing legitimate internet traders be required to sign up to one of the security schemes as noted above, but consumers unaware of the threat from fraudulent and counterfeit medicines would automatically be protected.

With the help of popular credit card companies – including the banks – a similar approach would add another protective barrier. If financial transactions were stopped for all illegal online pharmacies, again consumers would automatically be protected. However, this may be a difficult task given the existence of credit card processing companies, and so increased regulation and enforcement will be required.

According to Google's policy with regard to prescription medicines or pharmacies: 'Posting is not permitted for the promotion of prescription medicine without valid PharmacyChecker approval. Google only accepts items for pharmacies that are based in the US or Canada.' This is a sensible and prudent policy. However, given the slippery nature of illegal online traders it is practically impossible to enforce successfully much of the time.

How can patients protect themselves?

As the research demonstrated, those most vulnerable to suffering the probable ill-effects of purchasing medicines online, are those for whom detecting substandard or counterfeit medicines is the hardest – the untrained, unsuspecting European consumer. In order to help European patients protect themselves from unscrupulous internet 'medicine' traders, the EAASM would like to make the following recommendations:

Consumer advice

1. Don't buy from sites that offer to sell you medicines without a prescription, or sell medicines that are not approved by The European Medicines Agency (EMA).

2. Don't buy from websites that do not have a registered pharmacist available to answer questions.
3. Don't buy from websites that offer 'bulk discounts', 'sample packs', 'new cure' or 'amazing results'.
4. If the website offers an 'online consultation', be very careful. Unlicensed websites often offer this service to make them look professional and legal.
5. Only buy from safe, reputable pharmacies. Make sure the online pharmacy is properly regulated. You can check this with your national regulator.

Corporate responsibility

Patient associations

Informing patients of the terrible risks of counterfeit medicines is essential to raise awareness and fight this global threat. Information leaflets, website updates, and regular news bulletins could be a good way to get this message across to as many patients as possible.

Who is responsible? All national and international patient associations.

Search engines

Warning consumers of the potential risk of visiting an illegitimate website, before they enter an online pharmacy will create a barrier to harm. When consumers enter medicine-related key words, a popup box asking them to verify the authenticity of the online pharmacy might prompt them to make potentially lifesaving checks prior to authorising payment. This would allow consumers to make an informed decision as to whether they will take the risk of purchasing medicines online, or enable them to better validate the, sadly, all too few legitimate online pharmacies.

Search engines should also develop software to filter out sites which are likely to be selling

counterfeits. This software should block search results from unauthorised online pharmacies, through the recognition of a specific code, or lack thereof, which is only provided to authorised websites.

Who is responsible? All search engines including Google, Yahoo!, MSN, ASK etc.

Customs

Increasing public protection measures through more frequent and thorough inspection of packages, to combat illegal delivery of POMs. National governments need to provide customs with the authority to actively search for and confiscate suspect packages. For example, it is illegal for customs to open suspect packages in France.

Who is responsible? Customs authorities and agencies in each country.

Professional pharmacy societies

Creating national databases which include URLs and information on all regulated online pharmacies, will allow consumers to find reliable websites from which to purchase POMs. These databases must be made known to the general public and advertised through a variety of media on a regular basis.

Who is responsible? National, local and regional pharmacy societies.

Political and legal action

Running national and international awareness campaigns will increase consumer knowledge and understanding of the danger of buying medicines from unregulated pharmacies.

Campaigns would serve as the main platform to provide guidance and practical information about purchasing medicines, regulated pharmacies, and how to be cautious when purchasing from online pharmacies.

Who is responsible? National and regional governments, and international governments such as the European Union and the European Parliament.

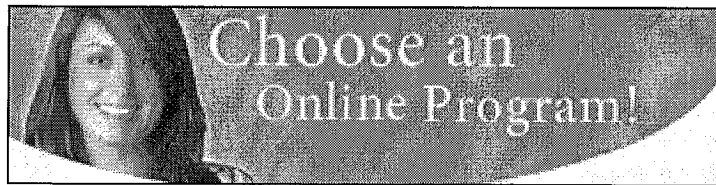
Financial restrictions

Better regulations for Electronic Payment Providers (EPPs) with penalties for breaking the regulations. Financial institutions should identify and block transactions related to websites selling counterfeit medicines.

Who is responsible? Banks, Credit Card companies, Payment providers (eg PayPal, Metacharge).

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<http://www.latimes.com/news/opinion/editorials/la-ed-tomato14-2008jun14,0,2320363.story>
From the Los Angeles Times

Fixing our food

The best way to protect consumers and producers is a system that will track what we eat.

June 14, 2008

Salmonella-contaminated tomatoes -- the latest evidence that all is not well with our food -- have not only sickened at least 228 people but unnecessarily tainted the reputation of an entire agricultural sector. As consumers recoil from all tomatoes, and restaurants pull them off the menu, perfectly good produce is unsalable. That includes tomatoes grown here in California, whose farms have been exonerated.

To some extent, this is simple panic. The U.S. Food and Drug Administration announced that cherry and grape tomatoes and those with the vine still attached are not implicated, but people are so frightened that they don't hear much beyond the words "tomato" and "warning."

But consumers also shun tomatoes because they can't get all the information they need to make safe choices. And that is the failure of the FDA and the industry to implement systems to track food from farm to grocery bag.

FDA investigators believe the bad tomatoes came from either Mexico or central Florida. They still have not located the trouble spot. Even if they had, it would not clear up consumers' questions. What good is it to consumers to know that California's tomatoes are in the clear? Unless they shop at a farmer's market, they have little way of learning where their fresh produce comes from.

We all have to peel those annoying stickers off most of our fresh produce before eating it. What if those stickers gave stores and consumers useful bar-coded information about the origins of their food? In the event of food poisoning, inspectors could determine almost immediately what producer was at fault and pull the bad food from the market, saving people from suffering -- and also saving the harvests of innocent growers.

In an interview with The Times' editorial board this week, FDA Commissioner Andrew C. von Eschenbach pointed to McCormick & Co., which buys most of its spices in India, as a company that already is tracking ingredients, using a low-tech labeling system on plastic bags that can trace peppers, for instance, back to their many producers. The simplicity and economy of the system allows it to be used even by a poor farmer tilling an acre of land.

It's up to Congress to provide the FDA with the funding for more inspection and safety technology. But a Government Accountability Office report released Thursday also blamed Von Eschenbach for failing to move on with the food protection plan he put forth in November 2007. Food poisoning acts quickly, and so must the federal government.

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